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EXAMINER

VIJAYAKUMAR, KALLAMBELLA M

ART UNIT PAPER NUMBER

1751

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/921,478

Applicant(s)

MUNSHI, M. ZAFAR AMIN

Examiner

Kallambella Vijayakumar

Art Unit

1751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Amendment in Paper-7, 06/18/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,26,28,30 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,26,28,30 and 37-42 is/are rejected.
- 7) ☒ Claim(s) 2-5,26,28 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Detailed Action

- Acknowledge the Amendment filed 06/18/2003 in Paper-7, and canceling Claims 6, 7, 27, 29, 31-36 and 43-48. Amended Claims 1-5, 26, 28, 30, and 37-42 are currently pending with the application.

Claim Objections

Claims 2-5, 26, 28, 30 are objected to because of the following informalities: as dependent on a rejected base Claim-1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim introduces a new limitation of "*is not an adhesive*", that has not been described in the specification nor claimed as a limitation in the earlier claims.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "not an adhesive" in claim 1 is a relative term which renders the claim indefinite. The term "not an adhesive" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The terms "adhesive" and "not adhesive" are relative terms, and the public will not be appeased about the boundaries of the limitations of the instant claims by the applicants, without undue burden of experimentation.

Claim Rejections - 35 USC § 103

The use of phrase "when used as a coating on an implantable cardiac stimulus electrode" in the claim-1 has not been treated with patentability. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The examiner construes this language as "Intended Use" and not treated with merits for patentability.

Applicant's arguments, see Paper-7, with respect to the rejection(s) of claim(s) 1-5, 26, 28, 30, and 37-42 under USC 102 (b) and USC 112 have been fully considered and are persuasive. Therefore, the claim objections, 112 and 102 (b) rejections based on Keusch et al (US Patent 5,354,790), 102(e/a) rejections based on Dozzhikov et al (Russian Patent # 2,086,217) and 103(a) rejections based on Dozzhikov et al (Russian Patent # 2,086,217) in view of Yamamoto et al (US Patent 4,515,162 or Hostettler (US Patent # 5,576,072) in Paper-4 have been withdrawn. However, upon further consideration, applicant's arguments filed in Paper-7 have not been not persuasive and the 103 rejections in Paper-4, dated 05/09/2003 in view of Keusch et al (US Patent # 5,354,790) have been maintained.

Claims 1-5, 26, 28, 30, and 37-42 rejected under 35 U.S.C. 103(a) as being unpatentable over Keusch et al (US Patent 5,354,790).

Keusch et al disclose an electro-conductive gel as a skin-interfacing member for the medical electrode comprising *PEO* with a molecular weight of 0.2×10^6 to 10×10^6 daltons, at a concentration of 7-35 wt % of in water and further containing 0.1-15 wt% electrolyte such as *NaCl* or *KCl*, wherein the *specific concentration of the electrolyte would depended on the desired conductivity* of the hydrogel (Col 21, Lines: 19-35, Col-22, Lines: 44-61), and this meets the limitations of the instant claims 1-4, 26, 37 and 39. Keusch et al also disclose the incorporation of various additives such as *stabilizers*, plasticizers such as glycerin, *pharmaceuticals and therapeutic agents*, in the hydrogel formulation (Col-16, Lines: 5-24), and the *electrically conductive transparent coating for medical electrodes* further comprising *silica as binder* and a mixed solvent of *propanol and water* (Col-2, Lines: 41-46; Col-4, Lines: 30-39),

that meets the limitations of instant claims 5, 28, 30, 38, 40-42. Keusch et al further disclose the use of hydrogel coatings for bio-electrodes for various applications including *defibrillation and implant*, which are similar applications that are intended use for, by the applicants (Col-26, Lines: 36-69).

Applicants argue that Keusch et al disclose a non-stingy adhesive hydrogel *which is more cohesive than adhesive* to the human skin that has explicitly *lower impedance value* than the instant claims by the applicants wherein the material is *not an adhesive* (Page-6, Para-III). Further, the compositions used by Keusch is almost identical to that claimed by the applicants and for similar applications. Keusch et al further disclose that the *non-stingy hydrogel with low tackiness/nonsticky* (Col-9, Line: 65; Col-10, Line: 3, Col-11, Lines: 1-5) could be coated on the medical electrodes including *defibrillation and implants*. Keusch et al further teach the variation in the adhesive properties of the hydrogels in terms of *Non-adhesive, non-stringy adhesive and highly adhesive* materials as a function of PEO molecular concentration and irradiation dose in megarads in Figures 1A and 1B.

Applicants argue that the impedance required by Keusch et al is lower than that claimed in the instant claims by the applicants 1 and 37. Although, Keusch et al differ slightly from the applicants in preferring the impedance of the mixture to be less than 100 ohms, the desired impedance requirement of less than 1000 ohms at 10 Hz - 5 MHz, it is of the same magnitude to that of the lower limit of 600 ohms measured at 100 Hz-100 KHz, and clearly reads on applicants lower limit. Keusch et al further suggestive of varying the type of the electrolytic materials and their amounts added to the mixtures, sufficient to produce conductive products, and the amount

of the electrolyte present may be effective to reduce transverse electrical resistance of the mixture, wherein the resistance could be adjusted based on the requirement.

It would have been obvious for a person of ordinary skill in the art to make modifications to the compositions and/or preparative methods of Keusch et al by choice of design, because both the compositions taught by Keusch et al and that claimed by the applicants are in the analogous art of coatings for medical electrodes, and to obviously arrive at the limitations of the instant claims by the applicants with reasonable expectation of success.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kallambella Vijayakumar whose telephone number is 703-305-


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4931. The examiner can normally be reached on M-Th, 07.30 - 17.00 hrs, Alt. Fri: 07.30-16.00 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Yogendra Gupta can be reached on 703-308-4708. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Kmv
September 22, 2003


YOGENDRA N. GUPTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700